

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

**Jose REMACLE et al.**

Confirmation No.: 7897

Application No.: 10/723,091

Art Unit: 1639

Filed: November 25, 2003

Examiner: Wessendorf, Teresa D.

For: **METHOD FOR STABILIZING PROTEINS ON A MICRO-ARRAY**

Attorney Docket No.: 4044.001

Customer No.: 000041288

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97 and §1.98**

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the following documents for the above-identified application. Except for copies of documents corresponding to U.S. Patents and U.S. Patent Applications, copies of the documents set forth below and listed on the attached Form PTO/SB/08 are provided herewith. A copy of an European Search Report is also provided herewith.

1. European Patent No. EP 0 336 231 A
2. U.S. Patent Application No. US 2003175827 A1
3. International Publication No. WO 9307466

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4. Great Britain Patent Application No. GB 2 016 687 A
5. International Publication No. WO 03050234
6. Japan Patent No. JP 61 189454
7. Japan Patent No. JP 03 084461

Document 1

European Patent Application No. EP 0 336 231 A entitled "Procedure for Stabilizing Biological Active Substances in Immobilized Form" published on October 11, 1989, in German.

In the European Search Report Document 1 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 2, other than an English language abstract:

Biologically active substances which are intended, for example, for immunodiagnosis and are in immobilized form must not lose their activity during the immobilization and the subsequent conversion into dry products and ought to retain their activity unchanged in the dried immobilized form for as long as possible. Dry products with improved activity and stability are prepared by drying the immobilized biologically active substances in the presence of a mixture of one or more sugar alcohols with a crystallization retarder, in particular in the form of hydrogenated oligosaccharides. Biochemistry, biotechnology and immunodiagnosis.

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Document 2

Document 2 is in the English language. In the European Search Report Document 2 was cited as in the "X" category of relevancy to claims 1-18.

Document 3

Document 3 is in the English language.

In the European Search Report Document 3 was cited as in the "X" category of relevancy to claims 1-18.

Document 4

Document 4 is in the English language.

In the European Search Report Document 4 was cited as in the "X" category of relevancy to claims 1-18.

Document 5

Document 5 is in the English language.

In the European Search Report Document 5 was cited as in the "X" category of relevancy to claims 1-18.

Document 6

Japan Patent No. JP 61 189454 entitled "Stabilized Immobilizing Antibody" published on August 23, 1986, in Japanese.

In the European Search Report Document 6 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 6, other than an English language abstract:

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PURPOSE: To obtain a dried immobilizing antibody which maintains the initial enzyme activity without deterioration even after the long-term preservation at a room temp. and is convenient for transportation, preservation, etc. by treating the immobilizing antibody with an aq. soln. contg. cane sugar or mannitol or a mixture composed thereof as a protective agent then drying the same thereby forming the antibody. CONSTITUTION: The immobilizing antibody is repeatedly subjected to the operation of bringing the immobilizing antibody into contact with the aq. soln. contg. the cane sugar or mannitol or the mixture composed thereof as the protective agent (the soln. contg a buffer soln. such as phosphoric acid-buffered physiological salt soln. as a solvent) and is then dried. The dried immobilizing antibody which maintains the initial enzyme activity without deterioration even after the long-term preservation at a room temp. and is convenient for transportation, preservation, etc. is thus obtd.

Document 7

Japan Patent No. JP 03 084461 entitled "Immunological Agglutination Reagent and Production Thereof" published on October 4, 1991, in Japanese.

In the European Search Report Document 7 was cited as in the "X" category of relevancy to claims 1-18.

Applicants are not aware of any English language document equivalent to Document 6, other than an English language abstract:

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PURPOSE: To improve the preservable stability of the above reagent by consisting the reagent of insoluble artificial carrier particles sensitized with an antigen or antibody, incorporating at least one kind of the compd. selected from albumin and dextran as a stabilizer therein and freeze-drying the same.

CONSTITUTION: Inorg. compd./dye composite particles having 1.2 to 2.0μm grain size and 1.2 to 2.0sp.gr. are preferable as the insoluble artificial carrier particles. Customary methods of physically adsorbing the antigen or antibody to the carrier particles, etc., are used for the sensitization of the antigen or antibody to the carrier particles. The albumins derived from man and bovine are more preferable as albumin to be used as the stabilizer. Dextrans of various mol.wt. are usable as the dextran if these dextrans are soluble in water. The content of the albumin and dextran is specified to about 3 to 20pts.wt. total of both per 5pts.wt. insoluble artificial carrier particles. The freeze-drying of the suspension of the immune material sensitized carrier particles added with the above- mentioned stabilizer is executed by the customary method.

The present Information Disclosure Statement is being filed after three months from the application's filing date and after the mailing date of the first Office Action on the merits, but before a final Office Action or Notice of Allowance (whichever is earlier) and, therefore, Applicants are filing concurrently herewith the Certification under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

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The submission of the listed document is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedated or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

  
John J. Martinez  
Reg. No. 48,254

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5111 Memorial Highway  
Tampa, Florida 33634-7356  
(813) 886-6085  
Dated: **February 3, 2005**

**Enclosures:** Copy of documents 1 and 3-7, copy of European Search Report.

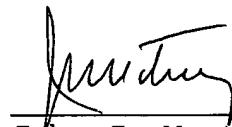
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**CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE**

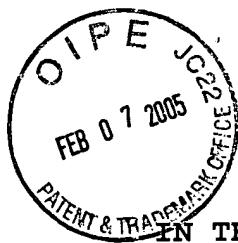
I hereby certify that the foregoing **INFORMATION DISCLOSURE STATEMENT** Form PTO/SB/08A, including seven (7) documents, for U.S. Application No. 10/723,091 filed November 25, 2003, were deposited in first class U.S. mail, with sufficient postage, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **February 3, 2005**.

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.



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John J. Martinez



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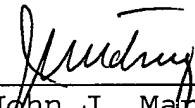
Alexandria, VA 22313-1450

Sir:

The undersigned hereby certifies:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

  
John J. Martinez  
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CERTIFICATION UNDER 37 C.F.R. §1.97(e)

ATTY. DOCKET: 4044.001

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing **CERTIFICATION** for U.S. Application No. 10/723,091 filed November 25, 2003, was deposited in first class U.S. mail, with sufficient postage, addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **February 3, 2005**.

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